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June 2, 2000

VIA FACSIMILE

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: Over the Counter Drug Products; Public Hearing (Docket No. 00N-1256), Request to Participate

Dear Sir or Madam

We have reviewed the notice of the above-mentioned public hearing, and respectfully request the opportunity to participate in the hearing scheduled for June 28-29, 2000. At this time, we do not intend to participate on behalf of any particular company. Rather, we wish to offer more general insights regarding the OTC monograph system based on our prior experience representing clients in this area, and given Mr. Pinco's past experience at FDA in the early development of the OTC monograph process.

In particular, we wish to comment on the following issues:

- The changing focus of the OTC Review from its original purpose;
- The need for expansion of the OTC Review in light of world harmonization efforts;
- Possible mechanisms for timely review of OTC ingredient petitions;
- The role of stakeholders in the development of FDA regulatory policy.

00N-1256

APE 66

We anticipate that these issues can be covered in approximately 15 minutes. If you have any questions or need further information, please feel free to contact us at the following numbers: Robert Pinco 887-4070, Mary Johnson 887-4588. After June 15, 2000, please contact us at the law firm of Buchanan Ingersoll, 1776 K Street, N.W., Ste. 800, Washington, DC 20006, phone 202-452-7900.

We appreciate the opportunity to participate in the hearing, and look forward to a thoughtful and productive discussion.

Sincerely,

Robert G. Pinco
Mary L. Johnson

MLJ

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THE LAW OFFICE OF ABDULAZIZ H FAHAD

FAX TRANSMISSION

June 2, 2000

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FROM: **Mary L. Johnson** PHONE: **887-4588** FLOOR: **12**

RE:

Comments/Special Instructions

CLIENT/MATTER NO. **079996..1443**

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